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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/021,403 | 12/12/2001 | Robert J. Schwartz | 108328.00031 (AVSI-0009) | 3652 |

25555 7590 12/28/2006

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DALLAS, TX 75202-3797

| EXAMINER | |
|---|---|
| HAMA, JOANNE | |
| ART UNIT | PAPER NUMBER |
| 1632 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 12/28/2006 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/021,403 | SCHWARTZ ET AL. | |
| | Examiner | Art Unit | |
| | Joanne Hama, Ph.D. | 1632 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *06 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,5-8,10,12-76,80-83,85 and 87-139* is/are pending in the application.

4a) Of the above claim(s) *14-75 and 89-136* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-8,10,12,13,76,80-83,85.87,88 and 137-139* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Applicant filed a response to the Non-Final Action of June 16, 2006 on October 6, 2006. Claims 2-4, 9, 11, 77-79, 84, 86 are cancelled. Claims 14-75, 89-136 are withdrawn. Claims 13, 88, 137-139 are amended.

Claims 1, 5-8, 10, 12, 13, 76, 80-83, 85, 87, 88, 137-139 are under consideration.

## ***Withdrawn Rejections***

### *Obviousness-type Double Patenting*

Applicant's arguments, see pages 16-20, filed October 6, 2006, with respect to the rejections of claims 1, 5-8, 10, 12, 13, 76, 80-83, 85, 87, 88, 137-139 have been fully considered and are persuasive. In particular, Applicant indicates at the bottom of page 18 to page 19, that although several known substances may, if combined, inherently have certain properties, that is not evidence that it would be obvious to one skilled in the art to make that combination. In the current application, the mere possibility that the vector of the 6,551,996 ('996) Patent could be operatively linked to a DNA fragment and subsequently introduced to a cell using the method of the 6,423,693 ('693) Patent in no way suggest that the result of this process would manifest itself in the offspring on the treated animal. The rejection of claims 1, 5-8, 10, 12, 13, 76, 80-83, 85, 87, 88, 137-139 has been withdrawn.

***35 U.S.C. § 102(e)***

Applicant's arguments, see pages 22-28 of Applicant's response, filed October 6, 2006, with respect to the rejection of claims 1, 5-8, 10, 12, 13, 76, 80-83, 85, 87, 88, 137-139 have been fully considered and are persuasive. In particular, Applicant indicates at the bottom of page 26 to page 27 that both Schwartz et al. and Aihara et al. disclose treating animals in general, not specifically females or males. The instant Application focuses on improving weight and growth in offspring only when female mammals are treated with the plasmids and methods of the instant invention. Thus, it cannot be said that the unintended production of "increased weight and growth in offspring" is an inevitable result of the teaching of the two cited references which do not make any distinction between males and females. The rejection of claims 1, 5-8, 10, 12, 13, 76, 80-83, 85, 87, 88, 137-139 has been withdrawn.

## ***New/Maintained Rejections and Objection***

### *Claim Objection*

Applicant is advised that should claims 10 and 85 be found allowable, claim 85 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

It is noted that neither claim 10 or 85 has been amended or cancelled and no response regarding this issue has been provided in Applicant's response, October 6,

2006. As such, Applicant is reminded that claim 85 will be objected to under 37 CFR 1.75 as being a substantial duplicate of claim 10.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 5-8, 10, 12, 13, 76, 80-83, 85, 87, 88, 137-139 are newly rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21-23 of Schwartz et al., U.S. Patent No. 6,423,693 ('693) in view of Aihara et al., 1998, Nature Biotechnology, 16: 867-870, previously cited, and in view of Kann et al., U.S. Patent 5,061,690.

Schwartz et al. teach that 100ug of pSK-GHRH plasmid was injected in adult immunocompetent C57BL6 mice (Schwartz, col., 26 under "Somatic Gene Transfer to

Skeletal Muscle in Vivo" to col. 27). hGHRH (human growth hormone releasing hormone) was detected in the systemic circulation after intramuscular injection of pSK-GHRH and mice expressing the plasmid exhibited increases in their total body mass (Schwartz col. 27, 5th parag.).

It is noted that Schwartz et al. do not specifically teach that the plasmid was introduced into mice by electroporation. However, Schwartz et al. teach that electroporation is one route of delivery of the vector (Schwartz et al., col. 12, line 40). Further, it is noted that Aihara et al. teach that in vivo electroporation provides an efficient approach for muscle-targeted gene expression (Aihara et al., page 869, 1st col., parag. under "Discussion").

It is noted that Schwartz et al. teach a system for obtaining larger animals via introduction of a GHRH plasmid into muscle, but do not specifically teach that the system was carried out in female mammals such that the female mammals gave birth to offspring that exhibited increased weight gain, compared to offspring born to untreated mothers.

However, Schwartz et al. teach that it was contemplated at the time of filing that their method had applications in pregnant mammals. Namely, Schwartz et al. teach that providing relatively small amounts of GHRH are required to stimulate the production and secretion of GH (growth hormone). Some benefits of increasing GH in non-human vertebrate include increased milk production in dairy cows and goats (Schwartz, et al., col., 2, 5th parag., also col., 35, lines 35-36).

While Schwartz is silent as to whether treatment of pregnant mammals with GHRH plasmid would necessarily result in offspring that exhibit increased weight gain, the offspring of treated mothers would have necessarily exhibited weight gain. For example, Kann et al. U.S. Patent 5,061,690 teach that pregnant ewes, administered hGRF protein, gave birth to lambs that were significantly heavier than lambs from untreated mother and had greater weight gain than untreated lambs (Kann et al., Table 1, in particular, see GRF2 and GRF1). It is noted that Kann et al. also teach that using GFR in pregnant ewes increases milk production (Kann et al., Table 2, in particular, see GFR1). Note that GRF is also known as GHRH (see sequence search printout, us-10-021-403a-8.rai., page 3).

Therefore, at the time of filing, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made, to electroporate a plasmid comprising a nucleic acid encoding GHRH into the muscle of a pregnant mammal in order to arrive at offspring that exhibit increased weight gain.

One having ordinary skill in the art would have been motivated to electroporate a plasmid comprising a nucleic acid encoding GHRH into the muscle of a pregnant mammal in order to arrive at offspring that exhibit increased weight gain.

There would have been a reasonable expectation of success given the results of Schwartz et al. for teaching that mice injected with a plasmid comprising a nucleic acid sequence encoding GHRH express high levels of GHRH in their plasma and for Kann et al. for teaching that administration of GRF (i.e., GHRH) to pregnant ewes during the third trimester results in larger lambs.

As such, claims 1, 5-8, 10, 12, 13, 76, 80-83, 85, 87, 88, 137-139 are rejected.

Claims 1, 5-8, 10, 12, 76, 80-83, 85, 87, 137-139 are newly provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/315,907 ('907) in view of babycenter [online], 2006 [retrieved on 2006-12-20]. Retrieved from the Internet:< URL: http://www.babycenter.com/refcap/pregnancy/pregcomplications/3073.html >, pages 1-5. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim of '907 is a genus of the instant claims. It is noted that while '907 does not discuss pregnant mammals, per se, claim 1 encompasses pregnant mammals as anemia can occur during pregnancy (e.g. see babycenter printout).

As such, the instant claims are species of claim 1 of '907. It is noted that treatment of anemia in pregnant women using the method of '907 would necessarily result in offspring that exhibit increased weight gain. For example, see above for Kann et al., U.S. Patent 5,061,690 teaching that increasing levels of GRF results in lambs that exhibit increased weight gain.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 5-8, 10, 12, 13, 76, 80-83, 85, 87, 88, 137-139 are newly provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20, 23-40, 43, 47, 48, 50, 51, 55-57, 59, 62, 65, 75-77, 82 of

copending Application No. 10/359,919 ('919). Although the conflicting claims are not identical, they are not patentably distinct from each other because while the focus of the instant Application is drawn to improving or enhancing growth in the offspring of a female mammal and the focus of '919 is to a method of changing the pituitary lineage in an offspring of a female mammal and to a method of elevating prolactin levels in an offspring, the method steps of administering a plasmid comprising a nucleic acid encoding GHRH to a pregnant female mammal, such that a biological effect occurs in the offspring, are the same. While the instant specification is silent as to whether the treatment has any effect on the pituitary or prolactin levels of the offspring, the steps of treating the offspring are the same between the two sets of claims and thus, the one treatment simultaneously results in the three kinds of biological effects.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. Note that the provisional rejection has been applied to the withdrawn claims of '919 as there is potential for the withdrawn claims to become patentable.

Claims 1, 5-8, 10, 12, 13, 76, 80-83, 85, 87, 88, 137-139 are newly provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 7, 9, 11-20, 22, 44, 45, 48-57, 63, 69, 75 of copending Application No. 10/764,818 ('818) in view of Kann et al., U.S. Patent 5,061,690 and in view of Aihara et al., 1998, Nature Biotechnology, 16: 867-870, previously cited. Although the conflicting claims are not identical, they are not patentably distinct from

each other because while the focus of the instant Application is drawn to improving growth in the offspring of a female mammal and the focus of '818 are to methods of decreasing an involuntary cull in farm animals and to increasing milk production in a dairy cow, the method steps of administering a plasmid comprising a nucleic acid encoding GHRH to a pregnant female mammal, such that a biological effect occurs in the offspring and the mother are the same. In particular with regard to the mother, Kann et al. teach that pregnant ewes administered GRF protein had increased milk production (Kann et al., Table 2). With regard to the offspring and that their involuntary cull is reduced, Kann et al. teach that lambs of GRF treated mothers were larger at birth and gained weigh faster than lambs from untreated mothers (Kann et al., col. 5-6, under "Birth weight" and "Growth of the lambs"). Note that GRF and GHRH are synonymous (see sequence search printout, us-10-021-403a-8.rai., page 3). With regard to the muscle tissue being penetrated with a plurality of needle electrodes, Aihara et al. teach that steel needle electrodes can be used to deliver plasmid (Aihara et al., page 870, 1st col., parag. "Electric pulse delivery and electrodes").

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. Note that the provisional rejection has been applied to the withdrawn claims of '818 as there is potential for the withdrawn claims to become patentable.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 137, 183 are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 137 and 138 have been amended to indicate that the vector is formulated with a polypeptide. However, a search of the specification did not indicate that "polypeptide" was used in formulating the vector. Further, Applicant does not indicate where in the specification support is provided. As such, claims 137 and 138 are rejected for including this new embodiment.

Claims 1, 5-8, 10, 12, 13, 76, 80-83, 85, 87, 88, 137-139 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of improving or enhancing weight gain in an offspring from a female mammal, wherein the female mammal is a farm mammal, comprising

introducing an effective amount of a vector directly into muscle cells of the female mammal prior to or during gestation of the offspring, wherein the vector is comprised of a nucleic acid sequence encoding growth hormone releasing hormone ("GHRH") or protein analog thereof, operably linked to a promoter and to a 3' untranslated region, wherein said nucleic acid sequence is expressed in the female mammal, and wherein

the expression of said nucleotide sequence results in improved or enhanced weight gain or rate of weight gain of the offspring, and wherein the vector is a plasmid,

does not reasonably provide enablement for

a method of improving or enhancing growth in an offspring from a female mammal, wherein the female mammal is a farm mammal, comprising

introducing an effective amount of a vector into muscle cells of the female mammal prior to or during gestation of the offspring, wherein the vector is capable of expressing a growth hormone releasing hormone ("GHRH") or protein analog thereof in the female mammal during gestation, wherein the vector comprises a promoter; a nucleotide sequence capable of expressing the GHRH or protein analog thereof; and a 3' untranslated region, under conditions that promote expression of the nucleotide sequence, and wherein the introduction and expression of the nucleotide sequence results in improved or enhanced growth in said offspring and wherein the vector is a plasmid.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, for reasons of record February 25, 2005, August 5, 2005, and June 16, 2006.

Applicant's arguments filed October 6, 2006 have been fully considered but they are not persuasive.

Applicant indicates that the Examiner had accepted the term "growth" in association with the instant invention in the previous Office Actions (Applicant's

response, page 20-21). In response, as indicated in the Office Action of June 16, 2006, the case had been reopened as the Examiner had reconsidered several issues. This was one such issue. Applicant indicates that the claims have been amended to read, "a method of improving or enhancing weight gain and development" (Applicant's response, page 21). However, none of the claims have been amended with this new phrasing. As such, the rejection, as it applies to this issue remains.

The Office Action, June 16, 2006, page 9, indicated that claim 139 encompasses a method of introducing a vector to muscle cells via any route, including intravenous administration. Applicant has not responded to this issue and thus, the rejection as it applies to the claim remains.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 5-8, 10, 12, 13, 76, 80-83, 85, 87, 88, 137-139 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al., U.S. Patent No. 6,423,693 ('693) in view of Aihara et al., 1998, Nature Biotechnology, 16: 867-870, previously cited, and in view of Kann et al., U.S. Patent 5,061,690.

The applied reference has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only

under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Note that the rejection as follows is the same as that written above in the Double Patenting rejection.

Schwartz et al. teach that 100ug of pSK-GHRH plasmid was injected in adult immunocompetent C57BL6 mice (Schwartz, col., 26 under "Somatic Gene Transfer to Skeletal Muscle in Vivo" to col. 27). hGHRH (human growth hormone releasing hormone) was detected in the systemic circulation after intramuscular injection of pSK-GHRH and mice expressing the plasmid exhibited increases in their total body mass (Schwartz col. 27, 5$^{th}$ parag.).

It is noted that Schwartz et al. do not specifically teach that the plasmid was introduced into mice by electroporation. However, Schwartz et al. teach that

electroporation is one route of delivery of the vector (Schwartz et al., col. 12, line 40). Further, it is noted that Aihara et al. teach that in vivo electroporation provides an efficient approach for muscle-targeted gene expression (Aihara et al., page 869, 1st col., parag. under "Discussion").

It is noted that Schwartz et al. teach a system for obtaining larger animals via introduction of a GHRH plasmid into muscle, but do not specifically teach that the system was carried out in female mammals such that the female mammals gave birth to offspring that exhibited increased weight gain, compared to offspring born to untreated mothers.

However, Schwartz et al. teach that it was contemplated at the time of filing that their method had applications in pregnant mammals. Namely, Schwartz et al. teach that providing relatively small amounts of GHRH are required to stimulate the production and secretion of GH (growth hormone). Some benefits of increasing GH in non-human vertebrate include increased milk production in dairy cows and goats (Schwartz, et al., col., 2, 5th parag., also col., 35, lines 35-36).

While Schwartz is silent as to whether treatment of pregnant mammals with GHRH plasmid would necessarily result in offspring that exhibit increased weight gain, the offspring of treated mothers would have necessarily exhibited weight gain. For example, Kann et al. U.S. Patent 5,061,690 teach that pregnant ewes, administered hGRF protein, gave birth to lambs that were significantly heavier than lambs from untreated mother and had greater weight gain than untreated lambs (Kann et al., Table 1, in particular, see GRF2 and GRF1). It is noted that Kann et al. also teach that using

GFR in pregnant ewes increases milk production (Kann et al., Table 2, in particular, see GFR1). Note that GRF is also known as GHRH (see sequence search printout, us-10-021-403a-8.rai., page 3).

Therefore, at the time of filing, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made, to electroporate a plasmid comprising a nucleic acid encoding GHRH into the muscle of a pregnant mammal in order to arrive at offspring that exhibit increased weight gain.

One having ordinary skill in the art would have been motivated to electroporate a plasmid comprising a nucleic acid encoding GHRH into the muscle of a pregnant mammal in order to arrive at offspring that exhibit increased weight gain.

There would have been a reasonable expectation of success given the results of Schwartz et al. for teaching that mice injected with a plasmid comprising a nucleic acid sequence encoding GHRH express high levels of GHRH in their plasma, Aihara et al. for teaching that in vivo electroporation provides an efficient approach for muscle-targeted gene expression, and for Kann et al. for teaching that administration of GRF (i.e. GHRH) to pregnant ewes during the third trimester results in larger lambs.

As such, claims 1, 5-8, 10, 12, 13, 76, 80-83, 85, 87, 88, 137-139 are rejected.

***Conclusion***

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service

center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

JH

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

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RESULT 5
US-09-122-171D-5
; Sequence 5, Application US/09122171D
; Patent No. 6423693
; GENERAL INFORMATION:
;  APPLICANT: Schwartz, Robert J.
;  APPLICANT:  Draghia-Akli, Ruxandra
;  APPLICANT:  Li, Xuyang
;  APPLICANT:  Eastman, Eric
;  TITLE OF INVENTION: GHRH Expression System and Methods of Use
;  FILE REFERENCE: 236/006 GeneMedicine
;  CURRENT APPLICATION NUMBER: US/09/122,171D
;  CURRENT FILING DATE:  1998-07-24
;  PRIOR APPLICATION NUMBER: 60/062,608
;  PRIOR FILING DATE: 1997-10-20
;  PRIOR APPLICATION NUMBER: 60/053,609
;  PRIOR FILING DATE: 1997-07-24
;  NUMBER OF SEQ ID NOS: 15
;  SOFTWARE: PatentIn version 3.1
; SEQ ID NO 5
;   LENGTH: 44
;   TYPE: PRT
;   ORGANISM: Bos taurus GHRH
US-09-122-171D-5

  Query Match             91.9%;  Score 182;  DB 4;  Length 44;
  Best Local Similarity   90.0%;  Pred. No. 6.5e-18;
  Matches   36;  Conservative    2;  Mismatches    2;  Indels    0;  Gaps    0;

Qy          1 HVDAIFTNSYRKVLAQLSARKLLQDILNRQQGERNQEQGA 40
              : |||||||||||| |||||||||||:|||||||||||||
Db          1 YADAIFTNSYRKVLGQLSARKLLQDIMNRQQGERNQEQGA 40


RESULT 6
US-09-122-171D-9
; Sequence 9, Application US/09122171D
; Patent No. 6423693
; GENERAL INFORMATION:
;  APPLICANT: Schwartz, Robert J.
;  APPLICANT:  Draghia-Akli, Ruxandra
;  APPLICANT:  Li, Xuyang
;  APPLICANT:  Eastman, Eric
;  TITLE OF INVENTION: GHRH Expression System and Methods of Use
;  FILE REFERENCE: 236/006 GeneMedicine
;  CURRENT APPLICATION NUMBER: US/09/122,171D
;  CURRENT FILING DATE:  1998-07-24
;  PRIOR APPLICATION NUMBER: 60/062,608
;  PRIOR FILING DATE: 1997-10-20
;  PRIOR APPLICATION NUMBER: 60/053,609
;  PRIOR FILING DATE: 1997-07-24
;  NUMBER OF SEQ ID NOS: 15
;  SOFTWARE: PatentIn version 3.1
; SEQ ID NO 9
;   LENGTH: 44
;   TYPE: PRT
;   ORGANISM: Capra hircus GHRH
US-09-122-171D-9

  Query Match             91.9%;  Score 182;  DB 4;  Length 44;
  Best Local Similarity   90.0%;  Pred. No. 6.5e-18;
  Matches   36;  Conservative    2;  Mismatches    2;  Indels    0;  Gaps    0;

Qy          1 HVDAIFTNSYRKVLAQLSARKLLQDILNRQQGERNQEQGA 40
              : |||||||||||| |||||||||||:|||||||||||||
Db          1 YADAIFTNSYRKVLGQLSARKLLQDIMNRQQGERNQEQGA 40


RESULT 7
US-08-442-029-6
; Sequence 6, Application US/08442029
; Patent No. 5756458
;  GENERAL INFORMATION:
;    APPLICANT:  Kubiak, Teresa M.
;    APPLICANT:  Friedman, Alan R.
;    TITLE OF INVENTION:  Stabilized, Potent GRF Analogs
;    NUMBER OF SEQUENCES:  12
;    CORRESPONDENCE ADDRESS:
;      ADDRESSEE:  Upjohn Company - Corp. Patents & Trademarks
;      STREET:  301 Henrietta Street
;      CITY:  Kalamazoo
;      STATE:  Michigan
;      COUNTRY:  USA
;      ZIP:  49001
;    COMPUTER READABLE FORM:
;      MEDIUM TYPE:  diskette (3M 5-1/4", DS double side 500 KB)
;      COMPUTER:  IBM PC compatible
;      OPERATING SYSTEM:  PC-DOS/MS-DOS
;      SOFTWARE:  WordPerfect 5.1
;    CURRENT APPLICATION DATA:
;      APPLICATION NUMBER:  US/08/442,029
;      FILING DATE:
;      CLASSIFICATION:  514
;    PRIOR APPLICATION DATA:
;      APPLICATION NUMBER:  US 07/614,170
;      FILING DATE:  14 No. 5756458 1990
;      APPLICATION NUMBER:  US 07/427,868
;      FILING DATE:  27 Oct 1989
;    PRIOR APPLICATION DATA:
;      APPLICATION NUMBER:  US 07/368,231
;      FILING DATE:  16 Jun 1989
;    PRIOR APPLICATION DATA:
;      APPLICATION NUMBER:  PCT/US90/02923
;      FILING DATE:  30 May 1990
;    ATTORNEY/AGENT INFORMATION:
;      NAME:  William G. Jameson
;      REGISTRATION NUMBER:  27,199
;      REFERENCE/DOCKET NUMBER:  4552.3 CP
;    TELECOMMUNICATION INFORMATION:
;      TELEPHONE:  616  385  7561
;      TELEFAX:  616  385  6897
;  INFORMATION FOR SEQ ID NO:  6:
;    SEQUENCE CHARACTERISTICS:
;      LENGTH:  45
;      TYPE:  amino acid
;      TOPOLOGY:  linear
;    FEATURE:
;      NAME/KEY:  C-terminally amidated homoserine residue
;      LOCATION:  Xaa45
US-08-442-029-6

  Query Match             91.9%;  Score 182;  DB 1;  Length 45;
  Best Local Similarity   92.5%;  Pred. No. 6.7e-18;
  Matches   37;  Conservative    3;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 HVDAIFTNSYRKVLAQLSARKLLQDILNRQQGERNQEQGA 40
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Db          1 YVDAIFTSSYRKVLAQLSARKLLQDILSRQQGERNQEQGA 40


RESULT 8
PCT-US91-09152-2
; Sequence 2, Application PC/TUS9109152
;  GENERAL INFORMATION:
;    APPLICANT:  Kubiak, Teresa M.
;    APPLICANT:  Sharma, Satish K.
;    TITLE OF INVENTION:  Fusion Polypeptides
;    NUMBER OF SEQUENCES:  42
;    CORRESPONDENCE ADDRESS:
;      ADDRESSEE:  Upjohn Company - Corp. Patents & Trademarks
;      STREET:  301 Henrietta Street
;      CITY:  Kalamazoo
;      STATE:  Michigan
;      COUNTRY:  USA
;      ZIP:  49001
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